HF1-35

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

T1398M

CFN: 1125262
98-BLT-34

Baltimore District
900 Madison Avenue
Baltimore, Maryland 21201
Telephone: (410) 962-4099

January 21, 1998

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Ms. Joyce Teets, Administrator
E. A. Hawse Health Center
P.O. Box 97, Route 55
Baker, West Virginia 26801

Inspection ID #2138270001

Dear Ms. Teets:

Your facility was inspected on December 16, 1997, by a representative of the West Virginia Environmental Health Services, Radiation Toxics and Indoor Air Division, under contract to the Food and Drug Administration (FDA). This inspection revealed that your facility failed to comply with the Quality Standards for Mammography (Standards), as specified in Title 21, Code of Federal Regulations, Part 900.12, as follows:

[redacted], **interpreting physician, did not meet the requirement of being board certified by any of the approved boards or having two months full-time training in the interpretation of mammograms.** [redacted] should immediately discontinue performing mammography until we have proof of his board certification or two-months full time training in mammography. All personnel records should be available at the time of the inspection for review. Please provide documentation showing that [redacted] was board certified or documentation showing two-months training in mammography.

[redacted] **did not meet the requirement of being licensed by the State of West Virginia to practice medicine.** [redacted] should immediately discontinue performing mammography until we have proof of a valid medical license. All personnel records should be available at the time of the inspection for review. Please provide documentation showing that [redacted] was licensed to practice medicine during the period of December 16, 1996 to December 16, 1997.

The specific deficiencies noted above appeared under the Level 1 heading on your MQSA Facility Inspection Report, issued at the close of the inspection. These deficiencies may be

symptomatic of serious underlying problems that could compromise the quality of mammography at your facility. Also, the following Level 2 findings have not been satisfactorily addressed by your facility:

[redacted] **did not meet the initial training requirement of having 40 hours of continuing medical education (CME) in mammography.** [redacted] must discontinue performing mammography until proper documentation of 40 CMEs, specifically in mammography, is documented. Interpreting physicians shall have 40 hours of documented CME, specifically in mammography. Time spent in residency specifically devoted to mammography will be accepted if the following criteria is met:

1) If [redacted] mammography medical education was completed prior to October 1, 1994, an attestation will be accepted as documentation.

2) If [redacted] mammography medical education was completed after October 1, 1994, a letter from his residency program will be accepted as documentation.

The documentation of 40 CMEs in mammography should be forwarded for our review prior to allowing [redacted] to perform independent mammography.

[redacted] **did not meet the requirement of having read and interpreted mammograms for the examinations of at least 240 patients in a 6-month period.** [redacted] should discontinue performing mammography until documentation can be provided showing they interpreted 240 patients in a 6-month period. Documentation should be forwarded for our review.

[redacted] **did not meet the continuing experience requirement of having read and interpreted mammograms from an average of 40 patient examinations per month over 24 months.** [redacted] should discontinue performing independent mammography until one of the following criterion is met:

1) Interpret mammograms under the direct supervision of a qualified radiologist to increase to 240 patients in a 6-month period.

or

2) Interpret mammograms under the direct supervision of a qualified radiologist so that [redacted] average patient exams are at the minimum of 40 per month.

It is your responsibility to ensure adherence to each requirement of the Mammography Quality Standards Act of 1992 (MQSA) and FDA's regulations. You are responsible for investigating and determining the causes of the deficiencies that the inspection identified and promptly initiating permanent corrective action.

If you fail to do so, FDA may, without further notice, initiate regulatory action. Under MQSA, FDA may:

- Impose civil money penalties on a facility of up to $10,000 for each failure to substantially comply with, or each day of failure to substantially comply with, the Standards;
- Suspend or revoke a facility's FDA certificate for failure to comply with the Standards;
- Seek an injunction in federal court to prohibit any mammography activity that constitutes a serious risk to human health.

Please note that FDA regulations do not preclude a State from enforcing its own mammography laws and regulations. In some cases, these requirements may be more stringent than FDA's. When you plan your corrective action, therefore, you should consider the more stringent State requirements, if any.

Within 15 working days after receiving this letter, you should notify FDA in writing of:

- The specific steps you have taken to correct all of the violations noted in this letter;
- Each step your facility is taking to prevent the recurrence of similar violations;
- Equipment settings (including technique factors), raw test data, and calculated final results, where appropriate; and

- Sample records that demonstrate proper record keeping procedures, if the noncompliances found relate to quality control or other records. (Note: Patient names or identification should be deleted from any copies submitted.)

If your facility is unable to complete the corrective action within 15 working days, please state the reason for the delay and the time within which the corrections will be completed.

Please send the original copy of your response to the Food and Drug Administration, Baltimore District, 900 Madison Avenue, Baltimore, Maryland 21201, to the attention of William L. Bargo, Acting Compliance Officer. Also, send a copy to the State radiation control office that conducted the inspection referenced in this letter. You may choose to address both FDA and State requirements in your response.

If you have any questions regarding this letter or how to ensure you are meeting MQSA standards, you may contact Lori A. Holmquist at (410) 962-3591, Ext.175.

Sincerely yours,

Elaine Knowles Cole
District Director

cc: West Virginia Environmental Health Services
Radiation Toxics And Indoor Air Division
815 Quarrier Street, Suite 418
Charleston, West Virginia 25301

Mr. Jim Potter, Director, Government Relations
American College of Radiology
1891 Preston White Drive
Reston, Virginia 22091